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AMAZON MALARIA INITIATIVE

SUCCESS STORY

PERU STRENGTHENS ITS MEDICINE QUALITY CONTROL APPROACH

Poor quality medicines that fail to meet official standards pose a significant threat to patients in need of quality-assured medicines to combat diseases such as malaria, for which proper treatment is essential to eliminate parasites from the blood effectively. Lack of quality-assured medicines can delay progress towards malaria control and eventual elimination.

From January to June 2015, 60% of 124 counterfeit products that were analyzed under orders from Peru's General Directorate of Medicines, Supplies and Drugs (DIGEMID) did not contain an active ingredient. These medicines could have been identified rapidly in the field with screening tests, allowing more prompt regulatory action.

In order to strengthen the capacity of Regional Health Directorate (DIRESA) staff and university labs, in August 2015 DIGEMID and the National Center for Quality Control (CNCC) convened a training workshop in Cuzco with the participation of six universities and six DIRESAs. Of the six DIRESAs in attendance, five (La Libertad, Ayacucho, Loreto, Tacna and Cuzco) had reported the highest rates of substandard and counterfeit medicines in the country.

During the workshop, CNCC trained participants on the use of rapid field tests. The head of Peru's National Institute of Health (INS) pointed out that field screening tests drastically reduce the time needed to assess medicine quality, from several months down to a few hours or days, depending on the number of samples to be analyzed. Expanding the use of rapid field tests for the monitoring of medicines at the decentralized level would allow for more prompt regulatory action and a larger volume of medicines screened.

Photo Credit: CNCC

Workshop participants received training on Level 2 of the Three Level Approach for medicines quality control, at the National University of San Antonio Abad's Pharmaceutical Technology Laboratory.

The methodology that Peru chose to adopt and began to scale up with the critically important August 2015 workshop is known as the Three Level Approach to medicine quality control. The Three Level Approach is a globally-proven methodology to detect substandard and counterfeit

Pan American Health Organization
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medicines in a rapid and cost effective manner. It consists of preliminary visual and physical inspection (Level 1), rapid screening field tests (Level 2), and compendial or other validated laboratory tests (Level 3).[1] It was first introduced in the Americas through the Amazon Malaria Initiative (AMI), by implementing partner USP's Promoting the Quality of Medicines Program.

Starting with the workshop in Cuzco, the six participating universities began the process of being integrated into a network to support the CNCC with supplemental technical and human resources for the decentralized quality control of medicines at the DIRESAs. The inclusion of university laboratories to cooperate with medicine quality monitoring in the field is intended to enhance Peru's capacity to ensure the quality of medicines on the market.

Also in 2015, Peru developed an annual timeline for the DIRESAs in Loreto and Madre de Dios to analyze the quality of a list of medicines. Medicine samples that fail field tests will be sent to the CNCC immediately to expedite confirmatory testing.

The involvement of universities in the August 2015 workshop demonstrates DIGEMID and CNCC's commitment to nationwide implementation of the Three Level Approach and to further strengthening the country's capacity to survey medicine quality in the field. Peru now has concrete plans to invest in long-term, sustainable solutions to facilitate the identification and removal of poor quality medicines from its territory, made possible with technical support provided through AMI.

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The Three Level Approach

The Three Level Approach applies sequential and complementary levels of quality control of increasing complexity, which are:

Level 1 – Visual and physical inspection

Level 2 – Rapid analytical screening tests that can be performed in the field

Level 3 – Registration methodologies that require an established lab and trained personnel

Photo Credit: PAHO/WHO

The Three Level Approach, developed by PQM to support countries' post marketing surveillance programs, was introduced and implemented initially in AMI countries through PQM assistance. Countries' implementation of Level 2 analysis helped to assess more than 1600 malaria medicines from 2005-2010.[2]

1. Pribluda VS, Barojas A, Coignez V, Brady S, Dijiba Y, et al. (2014) The Three Level Approach: A Framework for Ensuring Medicines Quality in Limited-Resource Countries. *Pharmaceut Reg Affairs* 3:117
2. Pribluda VS. Barojas A, Añez A, López CG, et al. (2012) Implementation of basic quality control tests for malaria medicines in Amazon Basin countries: results for the 2005–2010 period. Malaria Journal 11:202.

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